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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/688,672	10/10/2000	Yasir Skeiky	014058-009041US	2671

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EXAMINER
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SWARTZ, RODNEY P

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 11/17/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Applicati n N .

09/688,672

Applicant(s)

SKEIKY ET AL.

Examiner

Rodney P. Swartz, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 23July2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-27 and 105-115 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-27, 105-115 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 15.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

1. Applicants' Response to Office Action, received 23July2003, paper#14, is acknowledged. Claim 28 has been canceled. Claims 1, 4, 7, 9, 11, 12, 14, 15, 18, 22, 27, 105, 107, 109, 110, 111, 112, 113, and 114 have been amended.
2. Applicants' Supplemental Information Disclosure Statement, received 2June2003, paper#15, is acknowledged.
3. Claims 1-27 and 105-115 are pending and under consideration.

### **Rejections/Objections Moot/Withdrawn**

4. The objection to claim 18 because of "immungenic" is withdrawn in light of the claim amendment.
5. The rejection of claims 1-27 under 35 U.S.C. 112, first paragraph, written description, for pharmaceutical compositions, is withdrawn in light of the claim amendments.
6. The rejection of claim 28 under 35 U.S.C. 112, first paragraph, written description, for pharmaceutical compositions, is moot in light of the cancellation of the claim.
7. The rejection of claims 7-27 and 109-115 under 35 U.S.C. 112, second paragraph, as being indefinite for "an HTCC#1 antigen" or "a" full-length HTCC#1 antigen, is withdrawn in light of the claim amendments.
8. The rejection of claim 28 under 35 U.S.C. 112, second paragraph, as being indefinite for "an HTCC#1 antigen" or "a" full-length HTCC#1 antigen, is moot in light of the cancellation of the claim.
9. The rejection of claims 1-27 and 105-115 under 35 U.S.C. 112, first paragraph, scope of enablement for antigens from all other species of the tuberculosis complex, is withdrawn in light of the claim amendments.

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10. The rejection of claim 28 under 35 U.S.C. 112, first paragraph, scope of enablement for antigens from all other species of the tuberculosis complex, is moot in light of the cancellation of the claim.

### **Claim Rejections - 35 USC § 101**

11. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

12. Claims 1, 4, 7, 9, 15, 18, 22, and 27, as newly amended, are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Each of the listed claims originally were drawn to a "pharmaceutical" composition which denotes a manufacture, i.e., not a product of nature. However, the amendment of the claims deleted the recitation of "pharmaceutical", so that now the claims merely recite, "a composition".

One embodiment of the newly amended claim 1 reads as "A composition comprising an Mtb81 antigen from *Mycobacterium tuberculosis*, and an Mo2 antigen from *Mycobacterium tuberculosis*. Because the two antigens occur naturally in *Mycobacterium tuberculosis* and there is no recitation concerning isolation or purification, the claim reads of a product of nature.

One embodiment of the newly amended claim 4 reads as "A composition comprising a TbRa3 antigen from *Mycobacterium tuberculosis*, a 38 kD antigen from *Mycobacterium tuberculosis*, a TB38-1 antigen from *Mycobacterium tuberculosis*, and a FI TbH4 antigen from *Mycobacterium tuberculosis*. Because the antigens occur naturally in *Mycobacterium tuberculosis* and there is no recitation concerning isolation or purification, the claim reads of a product of nature.

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One embodiment of the newly amended claims 7 and 9 read as "A composition comprising an HTCC#1 antigen from *Mycobacterium tuberculosis*, and a TbH9 antigen from *Mycobacterium tuberculosis*. Because the two antigens occur naturally in *Mycobacterium tuberculosis* and there is no recitation concerning isolation or purification, the claim reads of a product of nature.

One embodiment of the newly amended claim 15 reads as "A composition comprising a TbRa12 antigen from *Mycobacterium tuberculosis*, and an HTCC#1 antigen from *Mycobacterium tuberculosis*. Because the two antigens occur naturally in *Mycobacterium tuberculosis* and there is no recitation concerning isolation or purification, the claim reads of a product of nature.

One embodiment of the newly amended claim 18 reads as "A composition comprising  $\geq 2$  antigen from a *Mycobacterium* species of the tuberculosis complex wherein the antigen is selected from the group consisting of MTb81.....and 85 complex. Because the listed antigens occur naturally in *Mycobacterium tuberculosis* and there is no recitation concerning isolation or purification, the claim reads of a product of nature.

One embodiment of the newly amended claim 22 reads as "The composition of claim 1, 4, 7, 15, or 18, further comprising  $\geq 1$  additional antigen from *Mycobacterium tuberculosis*, wherein the antigen is selected from the group consisting of MTb81.....and 85 complex. Because the listed antigens occur naturally in *Mycobacterium tuberculosis* and there is no recitation concerning isolation or purification, the claim reads of a product of nature.

One embodiment of the newly amended claim 27 reads as "The composition of claim 1, 4, 7, 15, or 18, further comprising an NS1 antigen from *Mycobacterium tuberculosis*. Because the listed antigens occur naturally in *Mycobacterium tuberculosis* and there is no recitation concerning isolation or purification, the claim reads of a product of nature.

**Claim Rejections - 35 USC § 112**

13. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

14. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15. Claims 1-27 and 105-115 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for whole antigens or fusion proteins consisting of whole antigens for use in diagnosis, treatment, or prevention of tuberculosis, does not reasonably provide enablement for immunogenic fragments or fusion products of immunogenic fragments. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The instant claims are drawn to compositions comprising either immunogenic fragments from *M. tuberculosis* or fusion polypeptides comprising said fragments. The application is directed to improved diagnostic reagents. However, the instant specification teaches only whole antigens as either compositions or fusion polypeptides. The instant specification is deficient in providing guidance for determining which "fragments" of the listed whole antigens are suitable for the improved diagnostic reagents. Therefore, the scope of the instant claims constitutes merely an invitation to determine which "fragments" fulfill the claimed inventions, and which combinations of such "fragments" are to become fusion polypeptides in order to fulfill the claimed inventions.

**Conclusion**

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16. No claims are allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., whose telephone number is (703) 308-4244.

The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (703)308-3909. The facsimile telephone number for the Art Unit Group is (703) 872-9306

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-2035.

  
RODNEY P SWARTZ, PH.D  
PRIMARY EXAMINER  
Art Unit 1645

November 17, 2003